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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/834,307	04/12/2001	Richard J. Whitbourne	P-1663-1	3036

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LIBERT & ASSOCIATES
3 MILL POND LANE
P O BOX 538
SIMSBURY, CT 06070-0538

EXAMINER

BENNETT, RACHEL M

ART UNIT

PAPER NUMBER

1615

DATE MAILED: 06/17/2002

7

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/834,307	WHITBOURNE ET AL.	
	Examiner	Art Unit	
	Rachel M. Bennett	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 September 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
 If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
 * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
 a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>4-6</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The examiner acknowledges receipt of the IDS filed on 7/26/01, 9/4/01, and 9/14/01.

Specification

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1-17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claims 1 and 12 recites the broad recitation "polymeric coating", and the claim also recites "med coat" which is the narrower statement of the range/limitation. Clarification is required.

Art Unit: 1615

Claim 1 and 12 are indefinite because Applicants do not define "extended period of time". It is suggested Applicants set an lower and upper limit regarding the period of time.

Claim 14 is indefinite because Applicants do not clearly define "major" and "minor" proportions. Is a major portion defined as more than 50% of the hybrid polymer coating? It is suggested Applicants use language with an upper and lower limit to define the proportions.

Clarification is requested.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1-2, 7-10, 12-17 are rejected under 35 U.S.C. 102(b) as being anticipated by Whitbourne et al. (US 5525348).

Whitbourne et al. discloses coating compositions comprising pharmaceutical agents such as anti-thrombogenic, and/or antimicrobial and/or pharmaceutical compositions containing heparin and/or antibiotics mixed with polymers (see abstract). Typical examples of polymers include insoluble cellulose esters, acrylic polymers. Claim 1 disclose a device comprising a substrate, and a coating compositions comprising a pharmaceutical agent in a concentration of from about 0.5% to about 99.5% by weight and a water-insoluble cellulose ester polymer, the coating composition being resistant to removal and having pharmaceutical activity under physiological conditions. Claim 3 disclose the water-insoluble cellulose ester polymer may be cellulose nitrate. Claim 5 further discloses the pharmaceutical agent may be an anticancer agent.

The device of claim 1 may further comprise polyvinylpyrrolidone (see claim 31). Claim 28 discloses surfactants selected from the group consisting of ionic polymers and polyacrylic acid. The water-insoluble polymers in the coating solution may range from about 0.01% to 20% by weight. Therefore, these claims are anticipated.

Claim Rejections - 35 USC § 103

5. Claims 1-10, 12-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Whitbourne et al. (US 5525348).

Whitbourne et al., as disclosed above, teaches coating compositions comprising pharmaceutical agents such as anti-thrombogenic, and/or antimicrobial and/or pharmaceutical compositions containing heparin and/or antibiotics mixed with polymers (see abstract).

Whitbourne does not teach the device to comprise at least 5 to 500 µg of at least one therapeutic agent.

The instant claims differ from the reference by reciting various doses of the active ingredient(s). However, the preparation of various pharmaceutical formulations having various amounts of the active agent is within the level of skill of one of ordinary skill in the art at the time of the invention. It has also been held that the mere selection of proportions and ranges is not patentable absent a showing of criticality. *In re Russell*, 439 F. 2nd 1228, 169 USPQ 426 (CCPA 1971). Thus, absent unexpected results, it is the position of the examiner that it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the amount of therapeutic agent.

6. Claims 1-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Whitbourne et al. (US 5525348), and further in view of Whitbourne (US 6306176).

~~Whitbourne et al., as disclosed above, teaches coating compositions comprising~~
pharmaceutical agents such as anti-thrombogenic, and/or antimicrobial and/or pharmaceutical
compositions containing heparin and/or antibiotics mixed with polymers (see abstract).
Whitbourne does not teach the device to comprise an acrylate polymer and PVP/VA copolymer
in a weight ratio in the range of 1.5:1 to 7:1.

~~Whitbourne disclose bonding layers for medical device surface coatings. Classes of~~
polymers, which may be used in the coating, include acrylic polymers and copolymers, vinyl
polymers and copolymers such as polyvinylpyrrolidone and polyvinylpyrrolidone polyvinyl
acetate copolymers.

Absent unexpected results, it would have been obvious to one of ordinary skill in the art
at the time the invention was made to have modified the composition of Whitbourne ('348) by
substituting PVA/VA for PVP as taught by Whitbourne ('176) because of the expectation of
obtaining similar results without undue experimentation. Whitbourne ('176) discloses both PVP
and PVA/VA may be used in a coating layer on a medical device. Therefore, it would be
obvious to substitute PVP/VA for PVP and determine a suitable ratio of PVP/VA to an acrylate
polymer (surfactant) in order to obtain the desired release rate of the active ingredient.

7. The prior art made of record and not relied upon is considered pertinent to applicant's
disclosure include Whitbourne (US 5997517) and Whitbourne et al. (US 5069899).

Correspondence

Any inquiry concerning this communication or earlier communications from the
examiner should be directed to Rachel M. Bennett whose telephone number is (703) 308-8779.
The examiner can normally be reached on Monday through Friday, 8:00 A.M. to 4:30 P.M..

Art Unit: 1615


If attempts to reach the examiner by telephone are unsuccessful, the examiner's

supervisor, Thurman K. Page can be reached on (703) 308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3592 for regular communications and (703) 309-7924 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding

should be directed to the receptionist whose telephone number is (703) 308-1234.

R. Bennett
June 5, 2002


THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600